UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,680	01/09/2002	Hans-Peter Schwarz	R-222.00	7064

7590 07/25/2003

Michael F Fedrick
Baxter Healthcare Corporation
PO Box 15210
Irvine, CA 92623-5210

EXAMINER	
MAYES, LAURIE A	
ART UNIT	**PAPER NUMBER**
1653	7

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831,680	Applicant(s) SCHWARZ ET AL.	
	Examin r Laurie Mayes	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 includes the acronym RAP. The applicant must insert the full name of RAP, namely, receptor associated protein, in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how a preparation according to claim 1 that is derived from human plasma, plasma fraction or a cell culture supernatant would differ from each other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yakhyaev et al. (Blood 90 (10) Suppl. 1:31a (1997)). Yakhyaev et al. teach a model system using mouse embryonic fibroblasts expressing LRP (low density lipoprotein receptor-related protein) wherein catabolism of the fVIII A2 domain is blocked by RAP and that the procoagulant activity of fVIIIa is regulated by both LRP binding and by the dissociation of its A2 subunit and

by RAP, which inhibits LRP binding to the ligands of fVIIIa. As hemophiliacs, including those with phenotypic hemophilia, are deficient in fVIII and as Yakhyaev et al. teaches that RAP impedes the clearance of fVIII which results in the retention of more fVIII, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to combine a set of fVIII and RAP (present claims 1, 3, 7, 11), whether obtained from human plasma, a plasma fraction or a cell culture supernatant (present claim 2), in a preparation to treat hemophilia. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claim 1-4, 6, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yakhyaev et al. as applied to claims 1-3, 7 and 11 above, and further in view of Nykjaer et al. (J. Biol. Chem. V. 267, N. 21 14543-14546 (1992)) and Anderson et al. (US 5,840,564). Nykjaer et al. teach that LRP helps to remove ligands, such as tPA, and transport them over the plasma membrane (p. 14546, col. 2, para. 1).

Anderson et al. teaches that aprotinin inhibits plasmin activity in a tissue-type plasminogen activator (col. 28, lines 55068 and col. 29, lines 1-15). Plasmin dissolves fibrin and other blood clotting factors. As tPA competes with fVIII for binding to LRP which clears away ligands and aprotinin inhibits plasmin activity in a tPA, it would have been obvious to one of ordinary skill in the art to administer to people having a coagulation disorder comprising fVIII deficiencies a combination of fVIII, aprotinin and tPA (present claims 4, 6, 10).

Claim 1-6, 7, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yakhyaev et al., Nykjaer et al. and Anderson et al. as applied to claims 1-4, 6, 7, 10 and 11 above, and further in view of Beguin et al. (Thrombosis and Haemostasis 78 (1), 590-594,

(1997). Beguin et al. teach that vFW acts as a blood coagulator and also as a carrier and stabilizer of factor VIII (see p.592 and applicant's specification on p. 3, para. 14). It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to administer to a person with a coagulation disorder, namely, with a vWF deficiency (present claim 8), a preparation comprising vWF to act as a blood coagulator and a combination of aprotinin which inhibits plasmin activity and tPA to compete with factor VIII already in the blood and vFW for binding to LRP for clearance (present claim 5). Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Conclusion

Claims 1-8, 10 and 11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
July 22, 2003

Christopher S. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600